

JUL 12 2000

SPECIAL 510(k) - CONFIDENTIAL
NUMED Z-5 ATRIOSEPTOSTOMY CATHETER

K0018041

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

June 14, 2000

Submitted By: NuMED, Inc., 2880 Main St., Hopkinton, NY 12965 (Ph) 315-328-4491

Contact Person: Nichelle LaFlesh

Device Name: NuMED Z-5 Atrioseptostomy Catheter; Class II

Predicate Devices: NuMED Z-5 Atrioseptostomy Catheter

Device Description: The NuMED Braided Atrioseptostomy Catheter is a new balloon catheter designed for the neonate with congenital heart disease requiring Atrioseptostomy. The catheter is coaxial in construction, 50cm in length with a 13.5mm non-compliant balloon on the distal end. The catheter features an inner lumen that will accommodate a 0.018" or 0.021" guidewire. The balloon is 13.5mm \pm 0.5mm in diameter and 1.35cm in length with an injection volume of 2cc. There is an imaging band under the balloon for accurate positioning in the left atrium. The catheter tip is angled at 35° to facilitate passage through the interatrial opening in the left atrium. To inflate the balloon to its maximum diameter, 2cc of diluted contrast media is pushed into the balloon extension after purging. The shaft of the catheter contains a stainless steel braiding to increase strength and pushability.

The non-compliant balloon and coaxial design of the NuMED Braided Atrioseptostomy catheter differs from previously marketed catheter:

- The catheter design is going from a dual lumen to a coaxial.
- The shaft material is changing from Pebax to Braided Pabax.

Biocompatibility Testing:

The materials used in the NuMED Atrioseptostomy Balloon Catheter are the same as those used in our PTA (K931009) and PTV Catheters (IDE #G890030) with the exception of the stainless steel, and which have been tested for biocompatibility in compliance with the Tripartite Biocompatibility Guidance for Medical Devices.

Test results indicate that all materials demonstrate the biocompatibility of the NuMED catheter and are on file at NuMED, Inc.

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Laboratory (Bench) Testing: All bench testing was performed in accordance with GMP's and the results are enclosed in a previous section

Intended Use: Used for the palliation of several congenital heart defects: transposition of the great arteries, total anomalous pulmonary venous drainage without pulmonary obstruction, tricuspid atresia, mitral stenosis, mitral atresia, and pulmonary atresia with intact ventricular septum..

Comparison Information:

MODEL:	NUMED	PREDICATE
Indications	Used for the palliation of several congenital heart defects: transposition of the great arteries, total anomalous pulmonary venous drainage without pulmonary obstruction, tricuspid atresia, mitral stenosis, mitral atresia, and pulmonary atresia with intact ventricular septum.	Used for the palliation of several congenital heart defects: transposition of the great arteries, total anomalous pulmonary venous drainage without pulmonary obstruction, tricuspid atresia, mitral stenosis, mitral atresia, and pulmonary atresia with intact ventricular septum.
Introducer:	6FR	6FR
Shaft Size:	5FR	5FR
Guidewire Size:	0.018" to 0.021"	0.018" to 0.021"
Usable Length:	50cm	50cm
Balloon Capacity	2.0cc	2.0cc
Inflated Diameter:	13.5mm	13.5mm
Balloon Length:	1.35cm	1.35cm
Max. Injection Pressure	600psi	600psi
Flow Rate:	4cc per second	4cc per second
Tip Angulation	35°	35°
Materials:	Shaft: Braided Pebax Balloon: Besno Image Band: Platinum	Shaft: Pebax Balloon: Besno Image Band: Platinum
Construction:	Coaxial construction with distally mounted non-compliant balloon. Distal lumen open to tip.	Dual lumen construction with distally mounted non-compliant balloon. Distal lumen open to tip.

These catheters are marketed for balloon atrioseptostomy. The parameters of the NuMED catheters are comparable to those of the currently marketed catheters.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 12 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Nichelle LaFlesh
Regulatory Affairs Manager
NuMed Inc.
2880 Main St.
Hopkinton, NY 12965

Re: K001804
Trade Name: NuMED Z-5™ Atrioseptostomy Cantheter
Regulatory Class: II (two)
Product Code: DXF
Dated: June 14, 2000
Received: June 15, 2000

Dear Ms. LaFlesh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

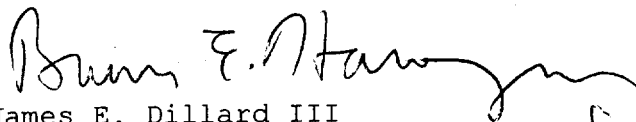
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Nichelle LaFlesh

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,


James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known):

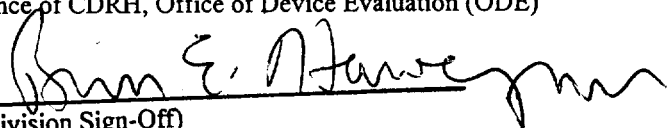
Device Name: **NuMED Z-5 Atrioseptostomy Catheter**

Indications For Use:

Used for the palliation of several congenital heart defects: transposition of the great arteries, total anomalous pulmonary venous drainage without pulmonary obstruction, tricuspid atresia, mitral stenosis, mitral atresia, and pulmonary atresia with intact ventricular septum.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number

K001804

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____

(Optional Format 1-2-96)